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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,419	06/07/2000	Tadashi Kohno	11127-002002	8455

7590

06/04/2002

Chris T Mizumoto  
Fish & Richardson PC  
Suite 2800  
45 Rockefeller Plaza  
New York, NY 10111

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/589,419

Applicant(s)

KOHNO ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/7/00; 10/18/00; and 3/20/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,6 and 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/401,739.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 2, filed 6/7/00, wherein the specification was amended; claims 25-42 were canceled; and claims 4-7, 10, 14, and 16-24 were amended.

**Note:** Claims 1-24 are pending.

### APPLICANT'S INVENTION

2. Applicant's invention is directed to <sup>13</sup>C-labeled compounds and uses thereof.

### RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election without traverse of Group I (claims 1-10) in Paper No. 9 is acknowledged. Thus, *the restriction is deemed proper and is hereby made FINAL.*

**Note:** Applicant is respectfully requested to cancel the claims directed to the non-elected groups.

### WITHDRAWN CLAIMS

4. Claims 2, 3, 6, and 11-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and/or species.

### 112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5: The claim as written is ambiguous because it is unclear what Applicant intends by the phrase '13C-labeled modifying group'. What group is Applicant referring to? Please clarify so that one may be able to readily ascertain what is being claimed.

Claim 10: The claim as written is ambiguous because of the phrase 'a derivative of the ...salt'. In particular, it is unclear what 13C-labeled oligosaccharides or polysaccharides the claim is directed to.

### 103 REJECTION

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4, 5, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jindrich et al (Carbohydrate Research, 1995, Vol. 266, pages 75-80) in view of DeRosch et al (US Patent No. 5,300,280).

**Jindrich et al** disclose the regioselectivity of alkylation of cyclomaltoheptaose (beta-cyclodextrin) and the synthesis of it mono-2-O-methyl, -ethyl, -allyl, and -propyl derivatives (see entire document). In addition, Jindrich et al disclose that partial

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methylation of cyclomaltoheptaose with  $^{13}\text{C}$ -enriched dimethyl sulfate is conducted in a dilute aqueous alkali solution (see abstract). Also, a series of experiments were performed wherein the partially methylated cyclomaltoheptaoses were subjected to methylation and  $^{13}\text{C}$  NMR data obtained (page 77, second complete paragraph; page 77, Table 2). While Jindrich et al disclose the labeling of cyclodextrin and the synthesis of some of its derivatives, the reference fails to disclose the labeling of additional modified derivatives of cyclodextrins.

**DeRosch et al** disclose a kit comprising cyclic oligosaccharides such as modified or unmodified cyclodextrin which may be labeled (see entire document, especially, abstract). Possible modified and unmodified cyclodextrins include alpha-, beta-, or gamma-cyclodextrin, hydroxypropyl-alpha-cyclodextrin, and sulfated-gamma-cyclodextrin to name a few (see column 3, lines 21-40).

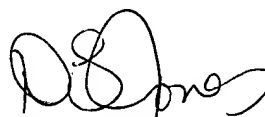
It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Jindrich et al using the teachings of DeRosch et al and generate modified cyclodextrins capable of being radiolabeled because DeRosch et al disclose both unmodified and modified cyclodextrins which are capable of being labeled. Thus, a skilled practitioner in the art would recognize that it is well known in the art (as indicated by DeRosch et al) to label cyclodextrin with a detectable label. Furthermore, since both Jindrich et al and DeRosch et al both disclose modified and unmodified cyclodextrin, the references may be considered to be within the same field of endeavor. Hence, the references are combinable.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones  
Primary Examiner  
Art Unit 1616

May 24, 2002